VI.C.

Further, on March 20, 1996, the *Federal Register* published notice of an additional 30 day comment period limited to specific documents the Agency added to the docket in support of the Agency's analysis of its jurisdiction. *See* 61 FR 11419 (Mar. 20, 1996). Although the Agency expressly limited the scope of the matters on which interested persons could comment, the March 20, 1996, action did provide the public with yet another 30 days on which to comment on issues related to such core subjects as the manipulation of the nicotine content of cigarettes and smokeless tobacco.

The Agency is not persuaded that any interested person has been unfairly prejudiced. First, FDA considers requests to extend the comment period on a case-by-case basis. Here, on the one hand, the commenter (the Tobacco Institute together with five major tobacco companies) presented in its request for additional time no compelling reasons to extend the period (such as a new, material study). On the other hand, FDA is faced with a matter raising serious public health concerns. For those reasons, the Agency denied the request to extend the period for as much time as the commenter had requested. *See* 60 FR 53560.

Second, each of the five tobacco companies that submitted this joint comment also filed suit against FDA immediately after FDA's Jurisdictional Analysis and notice of proposed rulemaking went on public display. The timing appears to indicate that these firms had been preparing to respond to an FDA proposal to regulate cigarettes and smokeless tobacco for some time. In any case, the cigarette manufacturers were able, jointly, to submit 2,000 pages of comments and 45,000 pages of exhibits and the smokeless tobacco manufacturers were able to jointly submit 474 pages of comments and 3,372 pages of exhibits within the time allotted for commenting on the Jurisdictional

Analysis and Proposed Rule. Their submissions far outweigh any others. The Agency, therefore, is not persuaded that these commenters suffered prejudice as a result of FDA's allowing twice as much time as the Agency's regulations require. *See Conference of State Bank Supervisors v. Office of Thrift Supervision*, 792 F. Supp. 837, 843 (D.D.C. 1992) (in light of the comments received, court declined to find that 30 day comment period was insufficient to allow opportunity for meaningful public participation); *Phillips Petroleum Co.*, 803 F.2d at 559 (citing cases in which courts have upheld notice periods of 45 days or less).

In sum, the Agency believes it provided ample additional time for comments—nearly 90 days more than is provided for in the Agency's own procedural regulation. Given that it received over 700,000 comments, including 95,000 distinct sets of comments, the Agency is not persuaded that the length of the comment period unfairly hampered the quality of the public debate on this matter.

D. THE NEED FOR "ADDITIONAL PROCEDURES"

Finally, one comment claimed that the Agency's use of William A. Farone's statement[1253] "and other similar documents" raises "serious issues of procedural fairness."[1254] The comment asserted that "FDA appears to treat" Farone as if he has current first-hand knowledge of internal company deliberations, and that FDA is using Farone's statement as "testimonial evidence." Based on this characterization of the

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[1253] William A. Farone was the director of applied research in the research and development department of Philip Morris U.S.A. *See* Farone WA, The Manipulation and Control of Nicotine and Tar in the Design and Manufacture of Cigarettes: A Scientific Perspective (Mar. 8, 1996), at 17. *See* AR (Vol. 638 Ref. 2).

[1254] Joint Comments of the Cigarette Manufacturers, Supplemental Comment on the Statement of William A. Farone (Apr. 19, 1996), at 15. *See* AR (Vol. 700 Ref. 223).

VI.D.

Farone report, the commenter argued that it should be allowed the opportunity to confront and cross-examine Farone on the record, examine any notes taken by FDA in interviews with Farone, and obtain an extension of the comment period in order to take Farone's deposition in a pending civil proceeding (to which FDA is not a party).[1255]

The Agency added the Farone statement and two affidavits from former tobacco industry employees as possible additional support (but by no means crucial) for the Agency's determination that it has jurisdiction over cigarettes and smokeless tobacco (because these products are intended for use as drug delivery devices). The comment failed to cite any legal authority to advance the proposition that, in making such a jurisdictional determination, the Agency must allow for cross-examination of witnesses and discovery of investigatory notes.

A brief review of the procedures the Agency employed in reaching its final jurisdictional determination is in order. At the same time that the Agency published notice of its proposal to regulate nicotine-containing cigarettes and smokeless tobacco, *see* 60 FR 41314, the Agency also published the results of its lengthy investigation into, and comprehensive analysis of, the Agency's jurisdiction over these products. *See* 60 FR 41453. Because of the unique importance of the jurisdictional issue, the Agency made its analysis available to the public, put the administrative record in support of its analysis on public display, and invited comments from the public on its analysis. When the Agency later supplemented the record in support of its Jurisdictional Analysis with the Farone

[1255] In a letter to Grossi PT, Jr., counsel for Philip Morris Inc., from Schultz WB, FDA deputy commissioner for policy, dated Apr. 12, 1996, the Agency responded to these very arguments. In addition to the Agency's discussion in that letter, the Agency offers the response in the text of this document. *See* AR (Vol. 711 Ref. 44).

report and two affidavits from former tobacco industry employees, the Agency invited public comment on these documents. *See* 61 FR 11419. Interested persons thus were provided the opportunity to present written statements consisting of facts, data, expert affidavits, studies, argument, and other relevant information with which to challenge, if they chose, the Agency's Jurisdictional Analysis and documents such as the Farone report that support it. Finally, in this document, the Agency is responding to all pertinent comments to the Agency's Jurisdictional Analysis.

FDA has primary jurisdiction to determine its jurisdiction. *Weinberger v. Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 627 (1973). At best, FDA must ensure that it meets "the rudiments of fair play" in determining its jurisdiction. *Id.* However, neither the Act nor the APA directs the Agency to commence a rulemaking proceeding, or conduct a formal evidentiary hearing, before making a jurisdictional determination. Nevertheless, FDA chose to employ the process outlined above—a notice and comment-type procedure—as a means by which to give the public an opportunity to participate the Agency's analysis of its jurisdiction and, thereby, met the conditions of "fair play."

There is nothing about the Farone report or the affidavits from former industry employees that would now require that the Agency employ even more procedures. In an ordinary informal rulemaking proceeding, such as that by which the Agency is promulgating its regulations governing cigarettes and smokeless tobacco, *see* 21 U.S.C. 371(a), an interested person generally has no right to cross-examine witnesses. *Compare* 21 U.S.C. 371(e) (enumerating those instances in which rulemaking under the Act may be subject to additional procedures, including the opportunity for a formal evidentiary hearing under sections 556 and 557 of the APA); *see Vermont Yankee Nuclear Power Corp. v.*

VI.D.

Natural Resources Defense Council, Inc., 435 U.S. 519, 524 (1978). Exceptions to this rule can be made where Congress has expressly provided for additional procedures, *see* 5 U.S.C. 553(c), or where the rulemaking proceeding is in fact a "quasi-judicial determination" in which "a very small number of persons are 'exceptionally affected, in each case upon individual grounds . . . .'" *Vermont Yankee Nuclear Power Corp.*, 435 U.S. at 542 (quoting *United States v. Florida East Coast Ry. Co.*, 410 U.S. 224, 242-245 (1973), and holding that the APA established "the maximum procedural requirements" that courts can impose upon agencies in conducting rulemaking procedures and that the circumstances in which courts may require additional procedures, "if they exist, are extremely rare"); *Lead Indus. Ass'n, Inc. v. EPA*, 647 F.2d 1130, 1169-1170 (D.C. Cir.) (interested persons face an extremely heavy burden when they demand that an Agency provide procedures not required by statute, such as cross-examination), *cert. denied*, 449 U.S. 1042 (1980).

The comment FDA received did not seriously attempt to show that the Agency is in fact engaged in the type of individualized determination described in *Vermont Yankee*, nor did it reference any statutory provisions that would require additional procedures in this instance. Instead, the comment rested its argument on the "testimonial" and "first-hand" nature of the Farone report. The mere labeling of evidence in this way does not change the nature of a proceeding. Indeed, the tobacco industry with their comments submitted statements of individuals as exhibits. Nor is the company-specific nature of the evidence determinative.

The issue, instead, depends upon the purpose for which the Agency intends to use the evidence. *See United Air Lines, Inc.*, 766 F.2d at 1119; *Ass'n of National*

Advertisers, Inc. v. FTC, 627 F.2d 1151, 1164-1165 (D.C. Cir. 1979), *cert. denied*, 447 U.S. 921 (1980). Where, as FDA has done here, the Agency is relying on evidence to reach essentially legislative judgments, for prospective application, and for the purpose of regulating an entire industry, there is overwhelming authority that an evidentiary hearing with cross-examination of witnesses is not required. *See, e.g., Vermont Yankee Nuclear Power Corp.*, 435 U.S. at 524; *Lead Indus. Ass'n,* Inc., 647 F.2d at 1169-1170; *United Air Lines, Inc. v. Civil Aeronautics Board*, 766 F.2d 1107, 1116-1121 (7th Cir. 1985); *Cleveland Elec. Illuminating Co. v. EPA*, 572 F.2d 1150, 1160 (6th Cir.), *cert. denied*, 439 U.S. 910 (1978); *Miami Nation of Indians of Indiana, Inc. v. Babbitt*, 887 F. Supp. 1158, 1173 (N.D. Ind. 1995).

The Agency is relying on documents such as the Farone report to support its jurisdiction over two broad categories of products (cigarettes and smokeless tobacco), and over all persons who manufacture, distribute, and sell these products. The Agency's inquiry into the operations of the leading tobacco firms was intended not to restrict or punish particular firms based on individualized grounds, but rather was intended to support regulatory controls that extend to the entire industry. Thus, the Agency's Final Rule governing youth access to cigarettes and smokeless tobacco products is properly characterized as rulemaking proceeding "in its purest form." *Vermont Yankee*, 435 U.S. at 542 n.16; *accord Lead Indus. Ass'n*, 647 F.2d at 1171 n.119. The fact, then, that Farone at one time worked for a leading tobacco firm does not change the purpose of this jurisdictional determination or in any way trigger the need for additional procedures. *See Commodity Exchange, Inc. v. Commodity Futures Trading Comm.*, 543 F. Supp. 1340, 1351 (S.D.N.Y. 1982) (summarizing case law holding that "informal rulemaking could

include an examination of past practice in order to prescribe future rules," and that "even when only one entity is the immediate subject of an Agency's action, this alone does not change its rulemaking nature . . ."), *aff'd,* 703 F.2d 682 (2d Cir. 1983).

The comment also complained that FDA's decision not to make available its interview notes with witnesses who have come forward with public statements (*i.e.*, Farone, Rivers, and Uydess) raised issues of "procedural fairness."[1256] This concern, however, is offset by the confidential nature of such material and by the limited extent to which the Agency relied on the public statements of Uydess and Farone. The public is entitled to notice of, and the opportunity to comment on, all materials upon which the Agency has relied. For that reason, the Agency published notice of the three witnesses' statements, placed the statements on the public docket, and afforded the public an opportunity to comment on them. The former employers of these witnesses, in particular, had the opportunity to challenge the witnesses' statements by affidavit or rebuttal documentation. The Agency has decided to cite to the publicly-released Uydess affidavit and the Farone report in this jurisdictional determination only to the extent it has on hand information from other sources that corroborates or confirms the information that Uydess and Farone have given.[1257] Therefore, the Agency has proceeded fairly in its use of these witnesses' statements.

The comment's suggestion that there should be public access to the notes and transcripts of the confidential interviews with these witnesses raises a fundamental issue

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[1256] Joint Comment of Cigarette Manufacturers, Comment (Apr. 19, 1996), at 16. *See* AR (Vol. 700 Ref. 223).

[1257] The Agency has decided not to rely on the Rivers affidavit in this document.

VI.D.

with implications that go beyond this jurisdictional determination. The Agency has broad authority to conduct investigations for the purposes of the Food, Drug, and Cosmetic Act. 21 U.S.C. 372 and 374. In conducting these investigations, it may be necessary for the Agency to pledge confidentiality to individuals who provide certain information and who fear retaliation if their identities are disclosed. Such disclosure may occur, directly, by naming them, or indirectly, by disclosing information only they could have provided. It is essential to the overall mission of the Agency that it sustain a reputation for maintaining the confidentiality of information given to it in confidence. Otherwise, the Agency risks losing invaluable sources of information which the Agency must have to carry out its statutory responsibilities. Moreover, disclosure of underlying investigatory materials may, in some instances, reveal the Agency's investigatory techniques, procedures, and methods, that it is entitled to shield from the public. *See* 5 U.S.C. 552(b)(7). In other instances, underlying investigatory materials may include trade secrets or other confidential commercial information, which the Agency is obligated to keep confidential. *See* 5 U.S.C. 552(b)(4). *See* generally 60 FR 66981, 66982 (Dec. 27, 1995) (the Agency's Statement of Procedures for Handling Confidential Information in Rulemaking); *see also* 5 U.S.C. 552(b)(6) and (b)(7). Thus, an express, unequivocal waiver of confidentiality on the part of a declarant would not necessarily obviate the Agency's obligation to protect such investigatory materials.

Information conveyed to the Agency during its interviews of these three witnesses, as reflected in the notes and transcripts of the interviews, includes the identification of other possible sources of information and other possible leads for the Agency to pursue, as well as trade secrets and other confidential commercial information. This information was

conveyed to the Agency with the understanding that it would be kept confidential. The Agency is duty-bound to honor its pledge of confidentiality, without which its investigation in this matter would have been severely hampered, and maintain its reputation as a reliable protector of confidential sources and information. The public interest is enhanced, and not harmed, by the Agency's commitment to honor this pledge, particularly where, as here, the Agency has afforded the public notice and an opportunity to comment on the only information given by these witnesses that the Agency is citing in its jurisdictional determination. *Cf. Lame v. Department of Justice*, 654 F.2d 917, 925 (3d Cir. 1981) ("[O]nce there has been an expressed or implied assurance of confidentiality, a subsequent release or publication by the government of a portion of the information does not negate the exemption for any of the information originally given.").

In light of the notice and opportunity for public comment afforded by the Agency with respect to the public statements of these three witnesses, the limited extent of the Agency's use of the Uydess affidavit and the Farone report, and the confidentiality concerns outlined above, the Agency properly declined to make its underlying interview notes and transcripts publicly available in the course of this proceeding.

Finally, the Agency does not agree that it was in any way required to delay this important public health proceeding in order for Farone's deposition to be taken. The Agency is not a participant in the civil litigation in which Farone may be called to testify and has no ability to influence the procedures to be followed in that proceeding, let alone the schedule. In any case, the Agency has no statutory obligation to delay a jurisdictional determination in order to allow for the submission of cross-examination testimony from a wholly separate proceeding.

E. CONCLUSION

Because of the importance of the issues involved, the Agency took the unusual step of inviting public participation in the process of developing the final jurisdictional determination set forth in this Annex. The result is the most extensive administrative record in the history of the Agency. FDA employed procedures that exceeded all legal requirements and gave the public the opportunity for full participation.

Dated: August 9, 1996

D J Kessler MD

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Commissioner of Food and Drugs